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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/989,796	11/20/2001	Michael Y. Zhang	ACSC 59931 (1987D)	1816

24201 7590 07/26/2005

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EXAMINER

BUI, VY Q

ART UNIT	PAPER NUMBER
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3731

DATE MAILED: 07/26/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/989,796

Applicant(s)

ZHANG ET AL

Examiner

Vy Q. Bui

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 09 May 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 26 and 28-37 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 26 and 28-37 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>5/9/2005</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 26 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. It is not clear if "the inflated outer diameter radial shrinkage" in the claim is measured based on two different inflated pressures (one in the balloon mold and another as a part of a catheter).

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 26, 28-29, 34-35 are rejected under 35 U.S.C. 102(b) as being anticipated by WANG et al. (5,556,383).

WANG (examples 1-2, table 1, for example) discloses balloons (examples 1-2, lines 1-2 of table 1) having a length of 2cm/20mm and radial distention % or shrinkage % from the inflated outer diameters of the balloons to the inner diameters of the molds at an ambient temperature (about 2.25mm in example 1: col. 5, lines 50-56, and about

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3mm in example 2: col. 6, lines 26-36) at 4.2% (example 1) or 3.2% (example 2) when inflated from 88 psi (6 atm) to 132 psi (9 atm).

Notice that when one gradually increases the internal pressure inside the balloon, WANG balloon is gradually expanded and when one gradually decreases internal pressure of WANG balloon, the balloon will shrink and achieve shrinkage percentage(s) as recited in the claims.

The balloons have been heat set in the balloon molds placed in hot water baths providing substantially uniform heating at 90 Celsius (example 1: col. 6, lines 3-24) or 95 Celsius (example 2: col. 6, lines 33-34). Notice that the balloon mold is **gradually** dipped into the hot bath so as to provide enough time for the heat to uniformly distribute to the balloon mold.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 30-33, 36-37 are rejected under 35 U.S.C. 103(a) as being unpatentable over WANG et al. (5,556,383).

As to claims 30-32, WANG (example 1 and table 1) discloses a polymeric balloon having substantial all structural limitation as recited in the claims, except for the axial growth is less than 6% or 10%. However, WANG discloses radial shrinkage less than 6% in a radial direction and the material of the balloon is substantially homogenous,

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therefore, it would be reasonable to expect the growth percentage in a same order to the radial shrinkage or less than 6% or 10%.

As to claim 33, WANG (example 1 and table 1) discloses a polymeric balloon of pebax (col. 5, lines 51) having substantial all structural limitation as recited in the claims, except for the balloon is made at least in part of a polyurethane. However, pebax and polyurethane are well-known low compliant polymeric materials suitable for manufacturing balloon in a balloon catheter. It would have been obvious to one of ordinary skill in the art at the time of the invention to have polyurethane as a material to make WANG balloon, as this configuration would guarantee a low compliant balloon with low shrinkage percentage.

As to claims 36-37, WANG (example 1 and table 1) discloses a polymeric balloon of pebax (col. 5, lines 51) having substantial all structural limitation as recited in the claims, except for the balloon thickness in the range as claimed. However, it would have been obvious to one of ordinary skill in the art at the time of the invention to make WANG balloon having a thickness in the range as recited in the claims for other applications requiring balloons with bigger sizes.

Response to Amendment

The amendment filed on 5/9/2005 under 37 CFR 1.131 has better defined the invention but is ineffective to overcome the WANG et al. (5,556,383) reference as indicated in the rejection presented above.


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Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Vy Q. Bui whose telephone number is 571-272-4692. The examiner can normally be reached on Monday-Tuesday and Thursday-Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anhtuan T Nguyen can be reached on 571-272-4963. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


07/22/2005

Vy Q. Bui
Primary Examiner
Art Unit 3731